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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/721,506 | 11/22/2000 | Thomas R. Cech | 015389-002610 | 5211 |

34151 7590 08/30/2004

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| EXAMINER | |
|---|---|
| SISSON, BRADLEY L | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1634 | |

DATE MAILED: 08/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/721,506 | CECH ET AL. | |
| | Examiner | Art Unit | |
| | Bradley L. Sisson | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *73,75-78,80,81,83-86,88,89,91-94,96 and 101-104* is/are pending in the application.

4a) Of the above claim(s) *73,80,81,88,89 and 96* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *75-78,83-86,91-94 and 101-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Specification*

1. The specification is objected to as documents have been improperly incorporated by reference. In particular, the specification states at page 268:

> All publications and patent documents cited in this application are incorporated by reference in their entirety for all purposes to the same extent as if each individual publication or patent document were so individually denoted.

Such omnibus language fails to specify what specific information applicant seeks to incorporate by reference and similarly fails to teach with detailed particularity just where that specific information is to be found in each of the cited documents. As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

> Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USQP 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.** *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference "expressly incorporates a particular part" of another reference); *National Latex Prods. Co. v. Sun Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a part of a later application); *cf. Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that **a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application**). (Emphasis added.)

Attention is also directed to MPEP 608.01(p)I, which, in pertinent part, is reproduced below:

> Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. (Emphasis added)

Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 83-86, and 91-94 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe

> an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

4. While applicant has amended so to remove language in claims 83 and 91 directed to fragment and variant, it is noted that dependent claims 84 and 92 still recite such embodiments. Accordingly, claims 83 and 91 are considered for purposes of examination to encompass such embodiments as a dependent claim can only further narrow, not broaden the scope of the claim from which it depends.

5. Claims 83-86, and 91-94 fairly encompass vast numbers of nucleic acid sequences, and cells that in turn are to encompass said vast numbers of nucleic acid sequences. As presently worded, the nucleic acids can be simply a "variant" or a "fragment: of an identified polynucleotide. No limitation has been placed on the degree of variability, or on the size of the fragment. Indeed, the "fragment" can seeming be as small as a single triplet, or codon, that would encode a single amino acid. Additionally, the claims fairly encompass variants that lack any activity. A review of the disclosure fails to find an adequate written description of the vast numbers of polynucleotides encompassed by the claims, and their associated cells. Additionally, the specification has not been found to provide an adequate written description of those polynucleotides that would encode a fragment or variant that would in fact be useful. The limited disclosure provided does not reasonably suggest that applicant was in possession of the genus of polynucleotides and cells encompassed by the claims. In support of this position,

attention is directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.
>
> ***
>
> We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

6. For the above reasons and in the absence of convincing evidence to the contrary, claims 83-86, and 91-94 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

*Response to argument*

7. At page 7, bridging to page 8 of the response received 14 May 2004 applicant asserts that this rejections, as well as the rejection under 35 USC 101 (*infra*) have all been overcome as a result of amendments to the claims. Argument is also presented that as a result of the claims reciting a certain percent identity, the protein must, by default, possess the TRT activity.

8. The above arguments have been fully considered and have not been found persuasive. As evidenced above, limitations directed to fragments and variants have not been removed from

all of said claims. To the extent that the claims still recite such embodiments, the rejection is maintained.

While agreement is reached in that the claims do now recite a certain percent identity requirement, the claims do not stipulate over how large an area this identity threshold must be observed. Further, there is no evidence of record that supports the position that all members of the claimed genus of protein would in fact possess this activity. Attention is directed to MPEP 2145.

> Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art.
> The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

9. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 75-78, 83-86, 91-94, and 101-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. For convenience, clams 75, 83, and 91, he only independent claims under consideration, are reproduced below.

75. *(Currently amended)* An isolated, synthetic, substantially pure, or recombinant polynucleotide comprising a nucleic acid sequence that encodes ~~the protein, variant or fragment of claim 73~~ a telomerase reverse transcriptase (TRT) protein, or the complement of said nucleic acid sequence ~~,~~ :

wherein said TRT protein has telomerase catalytic activity when complexed with a telomerase RNA; and contains an amino acid sequence that is at least 80% identical to SEQ. ID NO:2.

83. *(Currently amended)* An isolated, synthetic, substantially pure, or recombinant polynucleotide comprising a nucleic acid sequence that encodes ~~the protein, variant or fragment of claim 81~~ an TRT protein, or the complement of said nucleic acid sequence ~~,~~ .

wherein said TRT protein has telomerase catalytic activity when complexed with a telomerase RNA; and contains an amino acid sequence that is at least 90% identical to SEQ. ID NO:2.

91. *(Currently amended)* An isolated, synthetic, substantially pure, or recombinant polynucleotide comprising a nucleic acid sequence that encodes ~~the protein, variant or fragment of claim 89~~ an TRT protein, or the complement of said nucleic acid sequence.

wherein said TRT protein has telomerase catalytic activity when complexed with a telomerase RNA; and contains an amino acid sequence that is at least 80% identical to 500 contiguous amino acids in SEQ. ID NO:2.

13. As presently worded, the met and bounds of said claims is not readily discernable. In particular, it is not readily apparent as to the size/length of the region that the defined percent identity is to be observed.

14. The claims are also indefinite with respect to the metes and bounds of the "complement of said nucleic acid sequence." In particular, is the claim limited to the complete complement or is the claim to encompass something less than full length? If less, how much less. While

applicant has deleted explicit reference to fragments or variants, the claims still fairly encompass such embodiments, as they are not excluded.

15. The claims are also indefinite with respect to what percent identity the claimed nucleic acid needs to have to the complement.

16. Clams 84 and 92 lack antecedent support for "the protein, variant or fragment."

### *Claim Rejections - 35 USC § 101*

17. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

18. Claims 83-86, and 91-94 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

19. For purposes of examination, the claims have been interpreted as encompassing polynucleotides that encode "fragments" and "variants" of a telomerase reverse transcriptase protein whereby said protein is void of any activity. The only utility identified for the nucleic acid is for it to encode said telomerase reverse transcriptase protein, however, if the protein has no utility, the nucleic acid that encodes same also lacks utility. Applicant is urged to consider narrowing the claims' scope such that the variant and fragments so encoded by the claimed polynucleotide do in fact possess this activity, and thereby impart utility to the polynucleotide.

### *Claim Rejections - 35 USC § 102*

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

21. Claims 83-86, and 91-94 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhyu (*Journal of the National Cancer Society*, June 21, 1995, vol. 87, No. 12).

22. For purposes of examination, the claimed polynucleotide and cells claimed instantly have been interpreted as encompassing any polynucleotide that encodes virtually any telomerase reverse transcriptase protein, as well as any polynucleotide that encodes even a single amino acid found within any telomerase reverse transcriptase protein. Such breadth of scope is inferred from the usage of "variant" and "fragment," where the "variant" can be any variant, and the fragment can be of any size, and have any degree of similarity to the parent polynucleotide, including zero similarity.

23. Rhyu, page887, left column, discloses the cloning of human telomerase, and that telomerase activity has been found in cancer cells. The aspect of human telomerase having been cloned meets the limitation of an isolated polynucleotide, and that it encodes a variant or fragment of a telomerase. The polynucleotide so coned is considered to have as an inherent property at lest one codon that encodes at lest one amino acid found in a telomerase reverse transcriptase protein.

***Double Patenting***

24. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

25. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

26. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

27. Claims 75-78, 83-86, and 91-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,475,789. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a nucleic acid that encodes a protein having telomerase activity. Such breadth of scope is inferred as the nucleic acid of the instant application need only to be "isolated," which has been interpreted as encompassing embodiment from which the nucleic acid, it complementary sequence, etc., is simply removed from nature. Such breadth of scope is considered to encompass the nucleic acid being found in cells as well as it comprising additional sequences, e.g., a promoter.

28. Claims 75-78, 83-86, and 91-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-10 of U.S. Patent No. 6,261,836. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a nucleic acid that encodes a protein having telomerase activity. Such breadth of scope is inferred as the nucleic acid of the instant application need only to be "isolated," which has been interpreted as encompassing embodiment from which the nucleic acid, it complementary sequence, etc., is simply removed from nature. Such breadth of scope is considered to encompass the nucleic acid being found in cells as well as it comprising additional sequences, e.g., a promoter.

29. Claims 75-78, 83-86, and 91-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,093,809. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 75, 83 and 91 of the instant application fairly encompass the nucleic acid of claim 1 of the '809 patent.

*Response to argument*

30. At page 7 of the response received 14 May 2004, applicant asserts that the isolated nucleic acid having SEQ ID NO: 1 in the '809 patent (claim 1) does not encode a mammalian telomerase, and as such it does not have the identity requirements of the instantly claimed nucleic acids.

31. The above argument ahs been fully considered and has not been found persuasive for while claims 75 and 83 stipulate that the claimed nucleic acid encode a protein that either has the amino acid sequence SEQ ID NOO: 2 or be at lest 80% (claim 75) or 90% identical to same, the

claims leaves open the range of amino acids over which the percent identity is measured. Given such breadth of scope, claims of the instant application fairly encompass the invention of claim 1 of the '809 patent.

***Conclusion***

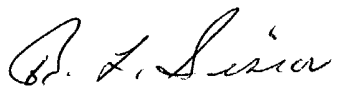
32. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

33. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

35. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

36. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
25 August 2004